PET VCAR
510 (k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h)

1. **Identification of submitter:**
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   Date Prepared: August 23, 2006

2. **Identification of Product:**

Device name	PET VCAR.
Classification name	Computed tomography x-ray system per 21 CFR 892.1750 Emission computed tomography system per 21 CFR 892.1200
Manufacturer/ Distributor	General Electric Medical Systems SAS 283, Rue de la Minière **78533 BUC Cedex France**

3. **Marketed Devices**
   PET VCAR is substantially equivalent to the devices listed below:

Model:	Volume Viewer Plus
Manufacturer:	General Electric Medical Systems
510 (k):	K041521

Model:	Advanced Lung Analysis II
Manufacturer:	General Electric Medical Systems
510 (k):	K042694

Model:	Advantage Fusion
Manufacturer:	General Electric Medical Systems
510 (k):	K983256

4. Device Description :

PET VCAR (Volume Computer Assisted Reading) is a PET/CT software package which can be used by the clinician to assist in diagnosis, staging, treatment planning and monitoring treatment response. The PET VCAR automatically highlights and bookmarks PET defined regions of interest based on user-defined threshold settings. The software can be used for visualization and analytical monitoring of disease progression or response to treatment or therapy using multi-exam comparison. The software is designed to measure Standard Uptake Value (SUV) and volume for any PET defined metabolic activity. The software automatically propagates bookmarks from one time point to another for the purpose of improving analysis and workflow. PET VCAR offers a tool called Interactive Data Analysis (IDA) spreadsheet that compiles and manages all the analytical information in an organized and interactive design. The IDA is synchronized with the image display layouts offering quick measurement / image visual validation. PET VCAR's workflow is designed to allow clinicians to make informed follow-up decisions in an efficient manner. PET VCAR does not provide or claim any automatic detection or automatic diagnosis of abnormal anatomy, structure or function.

The GE PET VCAR has to ensure relations with the following external systems:

Data Import

Image, exam and patient data can be imported in accordance with the DICOM Standard.

Data Export

Finding, exam and patient information can be exported in the Secondary Capture format of the DICOM standard that enables its storage on PACS systems.

Finding, exam and patient information can be exported in the Structured Report format of the DICOM standard that enables its display with DICOM SR compatible viewers.

Finding, exam and patient information can be exported in standard formats like HTML, XML, PDF, CSV, that enables its display with viewers compatible with the mentioned formats.

Configuration Requirements

PET VCAR is compatible with Advantage Windows Workstation™ 4.4 or higher

5. Indications for Use

PET VCAR (Volume Computer Assisted Reading) is a PET/CT software package which can be used by the clinician to assist in diagnosis, staging, treatment planning and monitoring treatment response. The PET VCAR automatically highlights and bookmarks PET defined regions of interest based on user-defined threshold settings. The software can be used for visualization and analytical monitoring of disease progression or response to treatment or therapy using multi-exam comparison. The software is designed to measure Standard Uptake Value (SUV) and volume for any PET defined metabolic activity. The software automatically propagates bookmarks from one time point to another for the purpose of improving analysis and workflow. PET VCAR offers a tool called Interactive Data Analysis (IDA) spreadsheet that compiles and manages all the analytical information in an organized and interactive design. The IDA is synchronized with the image display layouts offering quick measurement / image visual validation. PET VCAR's workflow is designed to allow clinicians to make informed follow-up decisions in an efficient manner. PET VCAR does not provide or claim any automatic detection or automatic diagnosis of abnormal anatomy, structure or function.

6. Comparison with Predicate Device

The functional features of PET VCAR software package are substantially equivalent to that of the following devices:

Device Name	FDA Clearance Number
Volume Viewer Plus	K041521
Advantage Lung Analysis II	K042694
Advantage Fusion	K983256

7. Adverse Effects on Health
The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:
- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

8. Conclusions

The PET VCAR does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the PET VCAR to be equivalent to those of Volume Viewer Plus (K041521), Advanced Lung Analysis II (K042694) and Advantage Fusion (K983256).

GE Healthcare
% Mr. Neil E. Devine, Jr.
Sr. Staff Engineer – Medical Devices
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

MAR 2 3 2007

Re: K063324
    Trade/Device Name: PET VCAR
    Regulation Number: 21 CFR 892.1750
    Regulation Name: Computed tomography x-ray system
    Regulation Number: 21 CFR 892.1200
    Regulation Name: Emission computed tomography system
    Regulatory Class: II
    Product Code: JAK and KPS
    Dated: March 7, 2007
    Received: March 8, 2007

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
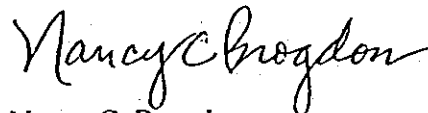
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
  Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _K063324_

Device Name: **PET VCAR**

Indications for Use:

PET VCAR (Volume Computer Assisted Reading) is a PET/CT software package which can be used by the clinician to assist in diagnosis, staging, treatment planning and monitoring treatment response. The PET VCAR automatically highlights and bookmarks PET defined regions of interest based on user-defined threshold settings. The software can be used for visualization and analytical monitoring of disease progression or response to treatment or therapy using multi-exam comparison. The software is designed to measure Standard Uptake Value (SUV) and volume for any PET defined metabolic activity. The software automatically propagates bookmarks from one time point to another for the purpose of improving analysis and workflow. PET VCAR offers a tool called Interactive Data Analysis (IDA) spreadsheet that compiles and manages all the analytical information in an organized and interactive design. The IDA is synchronized with the image display layouts offering quick measurement / image visual validation. PET VCAR's workflow is designed to allow clinicians to make informed follow-up decisions in an efficient manner. PET VCAR does not provide or claim any automatic detection or automatic diagnosis of abnormal anatomy, structure or function.
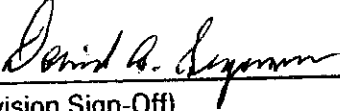
Prescription Use ___X____   AND/OR   Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)   (21 CFR 801 Subpart C)

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PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number _____